



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Secretary's Advisory Committee on Human Research Protections

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: Pursuant to the Federal Advisory Committee Act, notice is hereby given that the Secretary's Advisory Committee on Human Research Protections (SACHRP) will hold a meeting that will be open to the public. Information about SACHRP, the full meeting agenda, and instructions for linking to public access will be posted on the SACHRP website at <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>.

DATES: The meeting will be held on Wednesday, July 19, 2023 from 11:00 a.m. until 5:00 p.m., and Thursday, July 20, 2023, from 11:00 a.m. until 5:00 p.m. (times are tentative and subject to change). The confirmed times and agenda will be posted on the SACHRP web site as this information becomes available.

ADDRESSES: This meeting will be held via webcast. Members of the public may also attend the meeting via webcast. Instructions for attending via webcast will be posted at least one week prior to the meeting at <https://www.hhs.gov/ohrp/sachrp-committee/meetings/index.html>.

FOR FUTHER INFORMATION CONTACT: Julia Gorey, J.D., Executive Director, SACHRP; U.S. Department of Health and Human Services, 1101 Wootton Parkway, Suite 200, Rockville, Maryland 20852; telephone: 240-453-8141; fax: 240-453-6909; email address: SACHRP@hhs.gov.

SUPPLEMENTARY INFORMATION: Under the authority of 42 U.S.C. 217a, section 222 of the Public Health Service Act, as amended, SACHRP was established to provide expert advice and recommendations to the Secretary of Health and Human Services,

through the Assistant Secretary for Health, on issues and topics pertaining to or associated with the protection of human research subjects.

The Subpart A Subcommittee (SAS) was established by SACHRP in October 2006 and is charged with developing recommendations for consideration by SACHRP regarding the application of subpart A of 45 CFR part 46 in the current research environment.

The Subcommittee on Harmonization (SOH) was established by SACHRP at its July 2009 meeting and charged with identifying and prioritizing areas in which regulations and/or guidelines for human subjects research adopted by various agencies or offices within HHS would benefit from harmonization, consistency, clarity, simplification and/or coordination.

The SACHRP meeting will open to the public at 11:00 a.m., on Wednesday, July 19, 2023, followed by opening remarks from Julie Kaneshiro, Acting Director of OHRP and Dr. Douglas Diekema, SACHRP Chair. The meeting will begin with a discussion of IRB effectiveness, topic #4 of the recently published GAO report #GAO-23-104721, Institutional Review Boards: Actions Needed to Improve Federal Oversight and Examine Effectiveness. This will be followed by commentary on the FDA draft guidance, Decentralized Clinical Trials for Drugs, Biological Products, and Devices, in addition to discussion of recommendations that address the ethical conduct of decentralized clinical trials in human subjects research more broadly.

Discussion of both topics will continue on July 20, in addition to commentary on the recently released draft HHS guidance, *Frequently Asked Questions: Limited Institutional Review Board Review and Related Exemptions*. Other topics may be added; for the full and updated meeting agenda, see <http://www.dhhs.gov/ohrp/sachrp-committee/meetings/index.html>. The meeting will adjourn by 5:00 p.m. July 20, 2023. Time will be allotted for public comment on both days of the meeting. The public may submit written public comment in advance to SACHRP@hhs.gov no later than midnight July 12, 2023, ET. Written comments will be shared with SACHRP members and may

read aloud during the meeting. Public comment must be relevant to topics being addressed by the SACHRP.

Dated: June 12, 2023.

Julia G. Gorey,

Executive Director, SACHRP,

Office for Human Research Protections.

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